IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
SPARTANBURG DIVISION

STATE OF SOUTH CAROLINA Ex Rel. Henry McMaster, South Carolina Attorney General, Plaintiff,	§	
vs.	§	CIVIL ACTION NO. 7:09-387-HFF
ASTRA ZENECA PHARMACEUTICALS LP, ASTRA ZENECA LP, ASTRA ZENECA PLC, ASTRA ZENECA AB, ASTRA ZENECA UK LIMITED, Defendants.	§	

ORDER

I. INTRODUCTION

This case was filed as an action to recover funds expended by the State of South Carolina in providing medical treatment to Medicaid, South Carolina Department of Mental Health (SCDMH), and South Carolina State Employees Health Plan (SHP) participants suffering from Seroquel-related illnesses and to recover funds expended in purchasing Seroquel for uses not covered by the State's Medicaid, SCDMH, and SHP programs. Seroquel is an antipsychotic drug manufactured by Defendants. Currently pending before the Court are Plaintiff's motion to remand the case to state court and Plaintiff's motion to transfer the case to Judge Herlong. Having carefully considered the motions, the responses, the replies, the record, and the applicable law, it is the

judgment of this Court that the motion to remand will be granted, rendering moot the motion to transfer.

II. FACTUAL AND PROCEDURAL HISTORY

Attorney General Henry McMaster filed this lawsuit on behalf of the State of South Carolina in the Court of Common Pleas of the Seventh Judicial Circuit in Spartanburg County on January 9, 2009. In its complaint, Plaintiff alleges causes of action for submission of false and fraudulent claims under the Medicaid program, violations of the South Carolina Unfair Trade Practices Act, negligence, breach of warranty, fraud and misrepresentation, and unjust enrichment in connection with Defendants' marketing of Seroquel.

On February 13, 2009, Defendants removed the action to this Court, asserting that the case raises important federal questions arising under and requiring interpretation of certain federal laws, including the Food, Drug and Cosmetic Act (FDCA), the Food and Drug Administration Modernization Act (FDAMA), and the Medicaid statute. The same day, Defendants filed a motion to stay all proceedings in the case pending transfer by the Judicial Panel on Multi-District Litigation. On February 18, 2009, Plaintiff filed a motion to remand the case to state court, and on February 23, 2009, Plaintiff filed a motion to transfer the case to the Honorable Judge Henry Herlong because of Judge Herlong's prior experience in dealing with similar cases. On February 26, 2009, the Panel on Multidistrict Litigation issued a conditional transfer order, conditionally transferring this action and numerous others to the Middle District of Florida as part of the Seroquel MDL.[1] On March 12,

[1]Pursuant to Rule 7.4(e) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, conditional transfer orders do not become effective until filed with the clerk of the transferee district court. No such order has been filed in this case. Thus, the Court retains jurisdiction to entertain the pending motion to remand. *See also* Panel Rule 1.5 (noting that pendency of conditional transfer order does not in any way limit pretrial jurisdiction of court in

2009, the Court granted in part Defendant's motion to stay the case, staying all issues except the pending motions to remand and transfer.

III. STANDARD OF REVIEW

A party seeking removal bears the burden of establishing the existence of federal jurisdiction. *Mulachey v. Columbia Organic Chems. Co*, 29 F.3d 148, 151 (4th Cir. 1994). Because removal jurisdiction raises significant federalism concerns, a district court must strictly construe removal jurisdiction. *Id.* (citing *Shamrock Oil & Gas Corp. v. Sheets*, 313 U.S. 100 (1941)). Further, if federal jurisdiction is in doubt, remand to state court is necessary. *Mulachey*, 29 F.3d at 151. Moreover, when a sovereign State brings a claim, "considerations of comity make [the Court] reluctant to snatch cases which a State has brought from the courts of that State, unless some clear rule demands it." *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, 463 U.S. 1, 21 n. 22 (1983).

IV. CONTENTIONS OF THE PARTIES

It is undisputed that Plaintiff has failed to assert a federal cause of action explicitly on the face of its well-pleaded complaint. Defendants maintain, nonetheless, that this Court should exercise federal question jurisdiction because this cases raises "substantial questions of federal law." *Grable & Sons Metal Prods. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). In particular, Defendants contend that the Court cannot address the merits of Plaintiff's state law claims without substantially examining portions of the FDCA, the FDAMA and the federal Medicaid statute. Plaintiff responds that this action does not raise substantial questions of federal law as understood in *Grable*, because its state law claims do not involve contested federal issues. Furthermore,

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which action is pending).

Plaintiff contends that even if such issues do exist, the federal interest, as expressed by Congress, is insufficiently substantial to confer jurisdiction. Thus, Plaintiff insists that the case should be remanded to state court.

V. DISCUSSION AND ANALYSIS

A. Legal Framework

In considering whether to remand this action to state court, the primary issue the Court must resolve is whether subject matter jurisdiction exists over this action. If it does not, then remand is necessary. Both parties agree that if subject matter jurisdiction exists, it exists as federal question jurisdiction under 28 U.S.C. § 1331. The statute conferring federal question jurisdiction on this Court provides jurisdiction for all civil actions "arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Generally, "[a] suit arises under the law that creates the cause of action." *American Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260 (1916) (Holmes, J.). Thus, in most cases, federal question jurisdiction will be based on the presence of a federal cause of action on the face of the well-pleaded complaint. Such a cause of action is not present in this case.

However, the Supreme Court long ago recognized that federal question jurisdiction may also exist when state law claims present significant federal issues. *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180, 199 (1921). More recently, the Supreme Court clarified this exception to the general rule in its *Grable* decision. In *Grable*, the Court found federal question jurisdiction in a quiet title action that involved the interpretation of a federal tax statute. *Grable*, 545 U.S. at 314. In reaching this conclusion, the Supreme Court advised courts to ask, "does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may

entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id.* Defendants rely on the *Grable* exception as the basis for the Court's jurisdiction over this case.

B. Similar Cases in the District

Much of the debate in the parties' briefs concerns two previous cases involving similar facts, which were remanded to state court by the Honorable Henry M. Herlong. Both *State of South Carolina ex rel. Henry McMaster v. Eli Lilly & Company, Inc.*, No. 7:07-cv-1875-HMH, 2007 WL 2261693 (D.S.C. Aug. 3, 2007) (*Eli Lilly*), and *State of South Carolina ex rel. Henry McMaster v. Janssen Pharmaceutica Inc.*, No. 7:07-cv-1452-HMH, 2007 WL 2022173 (D.S.C. July 10, 2007) (*Janssen*), involved claims against pharmaceutical companies that manufactured antipsychotic drugs. Significantly, the causes of action asserted in Plaintiff's complaint are identical to those raised in *Eli Lilly* and *Janssen*. The primary differences between the complaints exist in the drug-specific allegations supporting each cause of action. Because of this similarity, Plaintiff maintains that this case should be remanded for the same reasons that Judge Herlong remanded the *Eli Lilly* and *Janssen* cases.

In response, rather than directly arguing that Judge Herlong erred in remanding *Eli Lilly* and *Janssen*, Defendants argue that this case was *removed on grounds different from* the removal grounds raised before Judge Herlong. Specifically, Defendants contend that Eli Lilly and Janssen never argued that "plaintiff's claims here involve important federal issues, including for example, free speech implications of so-called 'off-label' communications regarding prescription medicines, the complex regulatory scheme addressing such communications, and the propriety of civil claims by plaintiff for alleged violations of federal law concerning alleged off-label promotion of

prescription medicines." (Defs.' Memo in Resp. 2.)[2] Defendants insist that Plaintiff's claims are premised on the allegation that Defendants violated federal law through communications about non-FDA-approved (or "off-label") uses of Seroquel. Without going into any specifics about which federal statutes are implicated, Defendants maintain that the "legal issues concerning what is and is not permissible off-label communication under federal law are both complex and of constitutional dimension." (Defs.' Resp. 9.) The Court will address the merits of this argument below.

C. Defendants' "Off-label" Argument

For at least three reasons, Defendants' "off-label" argument in support of jurisdiction fails.

First, despite Defendants' contrary assertions, their argument that Judge Herlong never considered the potential significance of off-label communications to Plaintiff's state law claims is without merit. As Plaintiff points out, both Eli Lilly and Janssen argued that the State's allegations of "off-label" promotion implicated significant federal questions. (Pl.'s Reply 2-3.) More importantly, Judge Herlong rejected the "off-label" argument in both remand orders: "Thus, while the prescription of the drugs for such 'off-label' uses was the alleged goal-and the alleged harm-the submission of claims for non-medically accepted indications or non-medically necessary uses was not in and of itself the tortious conduct." *Eli Lilly*, 2007 WL 2261693 at *2; *Janssen*, 2007 WL 2022173 at *2. In short, Defendants' "off-label" marketing argument for removal was previously rejected in *Eli Lilly* and *Janssen*.

Second, even if Judge Herlong had never addressed the "off-label" argument, the Complaint, as pled by Plaintiff, is not about violations of federal law regarding "off-labeling." Plaintiff's thirty-

[2]"Off-label" uses are uses other than those for which a drug was approved by the FDA. *Washington Legal Found. v. Henney*, 202 F.3d 331, 332 (D.C. Cir. 2000).

eight page complaint uses the term "off-label" only once, and then it is used in the context of allegations of a pattern of fraudulent conduct rather than an independent violation of federal law. (Pl.'s Compl. ¶ 71.) A foundational principle of federal practice is that a plaintiff is the master of the complaint. *Johnson v. Advance Am.*, 549 F.3d 932, 937 (4th Cir. 2008) ("The plaintiff is master of his complaint, and this generally permits plaintiffs to avoid federal jurisdiction by exclusive reliance on state law.") (citations omitted). Likewise, "a defendant may not defend his way into federal court because a federal defense does not create a federal question under § 1331." *Nordan v. Blackwater Sec. Consulting, LLC*, 460 F.3d 576, 584 (4th Cir. 2006). In this case, Plaintiff's complaint asserts that Defendants committed Medicaid fraud by intentionally promoting non-medically necessary uses of Seroquel, which resulted in additional costs to the State through its Medicaid reimbursement to pharmacies. This claim arises under state law, and, as pled, has little, if anything, to do with "off-label" uses as that term is defined in federal law.[3]

Third, applying the *Grable* test, the Court finds that any references to "off-label" uses in this case are not "substantial enough" to justify the exercise of federal question jurisdiction. *See Grable*, 545 U.S. at 314 (noting federal issue must be "actually disputed and substantial"). Defendants argue that "plaintiff's prima facie case depends on proof of off-label promotion in violation of federal law." (Defs.' Resp. 18.) However, as discussed above, the Court disagrees. Plaintiff's prima facie case of state Medicaid fraud requires proof that Defendants made a false representation of a material fact or concealed or failed to disclose a material fact which affects the Defendants' right to payment or reimbursement under the state's Medicaid plan. S.C. Code Ann § 43-7-60. As alleged, Plaintiff

[3]Furthermore, although Defendants argue preemption in other contexts, in the context of "off-labeling," Defendants fail to argue that Plaintiff's claims are preempted by federal law. Thus, state law properly applies as pled by Plaintiff.

can establish a prima facie case of Medicaid fraud under state law without having to establish that Defendants' communications were "off-label" in violation of federal law.[4] In sum, Defendants' "off-label" argument for federal jurisdiction has already been rejected by Judge Herlong, it fails to appear on the face of Plaintiff's well-pleaded complaint, and it fails to present a substantial federal issue sufficient to justify the exercise of subject matter jurisdiction under *Grable*.

D. Whether Plaintiff's Claims Raise Substantial Questions of Federal Medicaid Law

In addition to their "off-label" arguments for jurisdiction, Defendants also assert that remand is improper because this case raises substantial federal questions under federal Medicaid law. However, these same arguments were rejected twice by Judge Herlong in *Eli Lilly* and *Janssen*, and the Court agrees that they should be rejected here. As Judge Herlong correctly noted,

> The Federal Medicaid Act allows states to "exclude or otherwise restrict coverage of a covered outpatient drug if . . . the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B) (West Supp. 2007). In addition, the Act defines the term "medically accepted indication." 42 U.S.C. § 1396r-8(k)(6) (West Supp. 2007). Thus, the Defendants argue that "a critical federal question presented by the complaint is whether prescriptions that the State alleges should not have been reimbursed were in fact authorized by – and required to be covered under – federal Medicaid law." [citation omitted]
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> The court finds that in the instant case, no substantial federal question exists to support a finding of jurisdiction. The Defendants' liability will solely depend upon their respective breach of duties as defined and created by state law. "Simply put, it is not the act of causing the submission of a claim for a non-medically accepted indication that creates liability under the state law causes of action,

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[4]The Court is focusing on Plaintiff's Medicaid fraud claims because Defendants appear to focus their off-label analysis on those claims. As noted above, Defendants, as the party seeking to establish jurisdiction, have the burden of proving that jurisdiction exists. Defendants fail to explain how Plaintiff's other state law causes of action involve significant "off-labeling" issues. Thus, the Court finds that Defendants have failed to meet their burden of establishing jurisdiction as to Plaintiff's remaining state law claims.

but rather the act of causing the submission of a false or fraudulent claim." *Pennsylvania v. Eli Lilly & Co., Inc.*, [511 F.Supp.2d 576, 582 (E.D. Pa. 2007).] For example, if the State proves at trial that the Defendants violated the Federal Medicaid Act, it would not necessarily follow that the Defendants committed Medicaid fraud as defined in S.C. Code Ann. §§ 43-7-60.

. . . .

Furthermore, even if the Defendants could demonstrate the existence of a substantial and contested federal question in the instant case, "the federal issue will ultimately qualify for a federal forum only if federal jurisdiction is consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of § 1331." *Grable*, 545 U.S. at 313-14. The Defendants have failed to make this showing.

In general, "the absence of a federal private right of action [is] evidence relevant to, but not dispositive of, the sensitive judgments about congressional intent that § 1331 requires." *Id.* at 318 (internal quotation marks omitted). However, in contrast to the facts in *Grable*, a finding of federal jurisdiction over any state cause of action implicating provisions of the Federal Medicaid Act and its accompanying regulations could "attract[] a horde of original filings and removal cases raising other state claims with embedded federal issues." *Id.* Under these circumstances, the fact that Congress provided no private right of action in the Federal Medicaid Act presents compelling evidence that a finding of federal jurisdiction in the instant case would not be "consistent with congressional judgment about the sound division of labor between state and federal courts." *Id.* at 313.

Further supporting this finding is the fact that the Federal Medicaid Act requires states to seek recovery of Medicaid funds from liable third parties. 42 U.S.C. § 1396a(a)(25) (West Supp. 2007); *see New York v. Lutheran Center for the Aging, Inc.*, 957 F. Supp. 393, 403 (E.D.N.Y. 1997) ("Where a federal statute such as Medicaid requires a state to enforce liability against a third party but does not provide the ground for that liability, nor require establishment of a ground for liability, federal question jurisdiction will not lie.") Therefore, a finding of federal jurisdiction in the instant case would not be "consistent with congressional judgment about the sound division of labor between state and federal courts." *Grable*, 545 U.S. at 313.

Janssen, 2007 WL 2022173 at *2-3.

Judge Herlong's analysis is consistent with many other courts who have remanded similar claims brought by states against pharmaceutical companies for recovery of Medicaid funds paid by the states. *See Arkansas ex rel. McDaniel v. AstraZeneca Pharm., L.P.*, No. 4:08CV00601 BSM, 2008 WL 3992746, at *1 (E.D. Ark. Aug. 25, 2008) (remanding similar Seroquel case to state court); *Arkansas ex rel. McDaniel v. Janssen Pharmaceutica, Inc.*, No. 4:07-cv-1210-WRW, 2008 WL 819019, at *1 (E.D. Ark. Mar. 25, 2008) (remanding case based on claims that mirror those asserted by Plaintiff); *Pennsylvania v. Eli Lilly & Co.*, 511 F. Supp. 2d 576, 581 (E.D. Pa. 2007) (remanding similar case to state court and noting "[e]ven though 'medically accepted indication' is defined by federal law, liability under the state law claims presented here nonetheless does not depend on the violation of any federal standard or statute."); *Hawaii v. Abbott Labs., Inc.*, 469 F. Supp. 2d 842, 852 (D. Haw. 2006) (remanding to state court claims for recovery of Medicare co-payments); *State of Missouri ex rel. Nixon v. Mylan Labs., Inc.*, No. 4:06CV603 HEA, 2006 WL 1459772 (E.D. Mo. May 23, 2006) (remanding case seeking damages for allegedly excessive reimbursement of Medicaid funds); *Wisconsin v. Abbott Labs.*, 390 F.Supp. 2d 815 (W.D. Wisc. 2005) (remanding to state court suit by state based on state law claims for, inter alia, Medicaid fraud and false representation); *State of Minnesota v. Pharmacia Corp.*, No. 05-1394, 2005 WL 2739297 (D. Minn. Oct. 24, 2005) (remanding case asserting claims for, inter alia, state Medicaid fraud and false advertising).

In contrast, the most analogous cases cited by Defendants in support of jurisdiction are all opinions of a single district judge in the context of the Zyprexa Multidistrict Litigation. *See e.g., Mississippi ex rel. Hood v. Eli Lilly and Co.*, Nos. 04-MD-1596 and 07-CV-645, 2007 WL 1601482 (E.D.N.Y. Jun. 5, 2007) (Weinstein, J.); *West Virginia ex rel. McGraw v. Eli Lilly and Co.*, 476 F.

Supp. 2d 230 (E.D.N.Y. 2007) (Weinstein, J.); *Louisiana ex rel. Foti v. Eli Lilly and Co.*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005) (Weinstein, J.). The Court is more persuaded by the majority of courts that have refused to exercise federal question jurisdiction under these circumstances.

E. Preemption Issues

Finally, Defendants urge the Court to factor into its jurisdictional analysis the federal issues, in the form of the Food and Drug Administration's labeling requirements, presented by Plaintiff's failure to warm claim. (Defs.' Resp. 17.) However, Defendants concede that a failure to warn preemption defense has never been held sufficient to convey federal jurisdiction. (Defs.' Resp. 17.) In fact, in its most recent term, the Supreme Court found that state products liability law was not preempted by FDA regulations, noting "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." *Wyeth v. Levine*, 129 S. Ct. 1187, 1200, 173 L. Ed. 2d 51, 66 (2009). Thus, even if Defendants' preemption argument were entitled to some weight under the *Grable* analysis, it still fails to rise to the level of significance necessary to justify federal question jurisdiction.

VI. CONCLUSION

To summarize, the Court is unconvinced by Defendants' arguments in support of jurisdiction. Furthermore, even when all their arguments are considered together, Defendants have still failed to meet their burden of showing that subject matter jurisdiction is proper.

Wherefore, based on the foregoing discussion and analysis, in light of principles of comity and federalism, and resolving any doubts in favor of remand, it is the judgment of this Court that

Plaintiff's motion to remand is **GRANTED**. Thus, Plaintiff's pending motion to transfer the case to Judge Herlong is rendered **MOOT**.

IT IS SO ORDERED.

Signed this 5th day of May, 2009, in Spartanburg, South Carolina.

s/ Henry F. Floyd
HENRY F. FLOYD
UNITED STATES DISTRICT JUDGE